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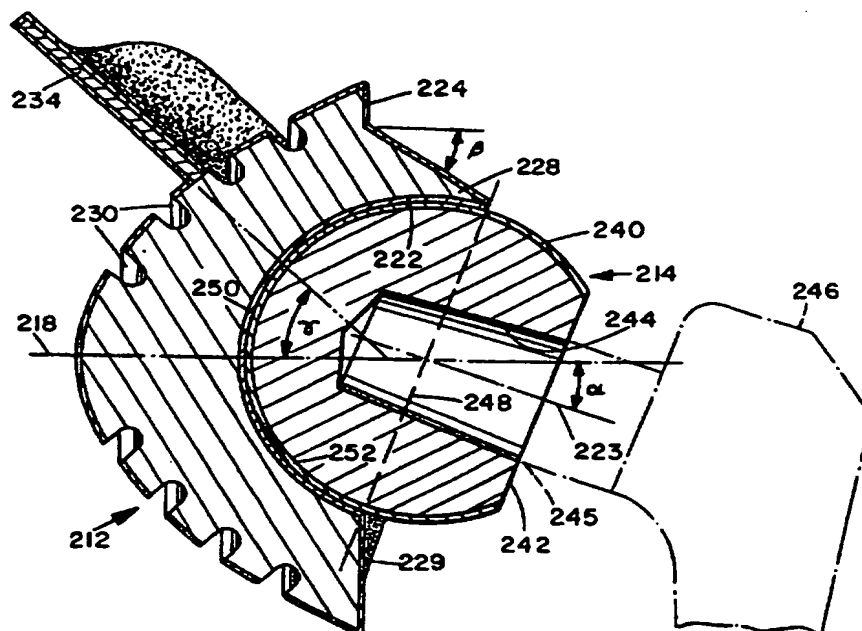
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(54) Title: PROSTHETIC JOINT AND METHOD OF MANUFACTURE



(57) Abstract

A prosthetic joint (200) for replacing a damaged natural joint in the body has a first socket part (212) having a concave, articulating surface (222) and a second part (214) having a convex articulating surface (240) for rotatable seating engagement in the concave surface (222). Both parts (212, 214) of the joint (200) are made from titanium alloy and have a coating layer (250, 252) of titanium nitride covering at least the articulating surface (222, 240) of each joint part (212, 214).

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PROSTHETIC JOINT AND METHOD OF MANUFACTURE

CROSS-REFERENCES TO RELATED APPLICATIONS

5 This application is a Continuation-In-Part of co-
pending application Serial No. 08/492,198 filed June 19,
1995, which was a Continuation of application Serial No.
08/218,708 filed March 25, 1994, now U.S. Patent No.
5,425,777, which was a Continuation of application Serial
10 No. 07/995,773 filed December 23, 1992, now abandoned.

BACKGROUND OF THE INVENTION

15 This invention relates to artificial or prosthetic
joints for implanting in the human body, or other animals,
to replace joints which have been destroyed or damaged by
injury or disease, and to a method of making such
artificial or prosthetic joints.

20 Any articulating joint in the body may be surgically
replaced if necessary, and joint replacement surgery has
been common for many years. Generally, a ball and socket
are made to reproduce the shape of the natural joint as
closely as possible. The natural joint is then removed,
and the prosthesis parts are attached to the adjacent bone
25 structures.

 One problem with such implants is that they must be
made of materials which are biocompatible with the human
body. In an artificial joint, two bearing surfaces must
continuously slide against each other, so the materials
30 used must additionally be wear resistant and not form
particles which are then carried away to other parts of the
body. The materials must also resist corrosion or
deterioration as a result of exposure to body fluids. The
majority of prosthetic joints are currently made with the
35 ball and socket of different materials, with one of the
materials being harder than the other. For example, one
part of the joint may be of plastic while the other part is

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metal. Due to wear of the softer, plastic part, these prostheses typically require replacement within five years.

Prosthetic joints made entirely of metal have been tested in the past, but these have generally been found unacceptable. Trials have been carried out using articulating surfaces such as ball and socket joints where each side of the joint is of chrome cobalt material, and stainless steel joints have also been tested. However, these joints have not been found acceptable due to various disadvantages, such as wear, rejection by the patient's body, and toxicity.

In all prosthetic joints in which one or both parts of the joint is of metal, the articulating surfaces are typically polished to a high degree of smoothness. Due to the smoothness and close fit between the articulating surfaces, lubrication is limited, and this also tends to lead to increased wear.

SUMMARY OF THE INVENTION

20

It is an object of the present invention to provide an improved prosthetic joint with better compatibility with the human body and improved wear characteristics.

According to one aspect of the present invention, a prosthetic joint is provided which comprises a first, socket part having a concave articulating surface and a second part having a convex articulating surface for rotatable seating engagement in the concave articulating surface of the socket part, both parts of the joint being of titanium alloy and at least the articulating surface of each joint part being coated with a layer of titanium nitride. Preferably, the entire outer surface of both joint parts is coated with titanium nitride, which has been found to have excellent biocompatibility and to be resistant to wear.

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In a preferred embodiment of the invention, the substrate material is an alloy of titanium, aluminum and vanadium, preferably TiAl64V, while the coating layer is of titanium nitride (TiN) or double nitride (TiNN). It has been found through extensive testing that titanium nitride will not particulate with articulation even over extended periods of time, and this material is also highly biocompatible, reducing the risk of rejection or other problems. By coating titanium nitride onto and into a titanium alloy, the coating becomes molecularly integrated with the titanium alloy material of the substrate, further reducing the risk of chipping or flaking, which has been a problem with previous joints in which a coating layer was applied over a metal substrate.

Preferably, the coating layer on each of the articulating surfaces is made with a precise degree of surface roughness. The roughness between the articulating surfaces will provide openings permitting joint fluid to flow between the articulating surfaces and lubricate the joint. This further improves operation of the joint and reduces wear. In a preferred embodiment of the invention, the surface was roughened to a #8 finish. This has been found to produce good articulation as well as wear resistance on extensive testing.

The joint may be designed to replace any body joint, such as a hip joint, knee joint, shoulder joint, elbow joint, wrist joint, finger joint, ankle joint, toe joint, and so on. The articulating surfaces are simply designed for the desired joint action. Typically, the joint parts are also provided with anchoring devices for embedding in the adjacent bone to secure the joint part in position. The anchoring devices may be spikes, lugs or the like and are preferably formed integrally with the respective joint part and of the same material. The form of the anchoring device will be dependent on the type of joint to be replaced.

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Preferably, the dimensions of the cup or socket are different from those of the ball or convex articulating surface. In a preferred embodiment of the invention, the concave surface of the first joint part had a diameter slightly greater than that of the convex surface, typically around three thousandths of an inch larger than the convex surface. Additionally, the rim of the convex surface preferably has a diameter slightly less than the remainder of the convex surface, typically around 1/1000 less. By making the rim of the convex or male joint part slightly smaller in diameter, a gap is provided to allow joint fluid to lubricate the articulating surfaces.

According to another aspect of the invention, a method of making a prosthetic joint is provided, which comprises forming a first socket part of titanium alloy material, the first socket part having a concave articulating seat, forming a second, ball part of the same titanium alloy material as the socket part, the ball part having a convex articulating surface for rotating engagement in the concave seat, machining both articulating surfaces to a desired surface finish to a predetermined degree of roughness, and deposition of a layer of titanium nitride onto each of the articulating surfaces by physical vapor deposition (PVD).

In physical vapor deposition techniques such as sputtering or cathodic arc deposition, the coating material is placed into a vacuum chamber which is filled with a working gas, such as argon, to a pressure adequate to sustain a plasma discharge. The coating material is then bombarded with ions from the plasma, causing physical vapor deposition of atoms of the coating material. The substrate to be coated is placed to intercept the flux of molecules of TiN material, and the TiN material condenses onto the substrate to form a coating. Preferably, a surface roughness of #8 on the roughness scale is provided, and the thickness of the coating layer on each articulating surface is 3 to 3.5 microns.

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The substrate and coating materials have been found to be highly biocompatible and resistant to wear, corrosion or degradation when exposed to body fluids. The joint has been tested at extremely high pressures and has been found to be resistant to particulation at all pressures expected to be found at any joint site in a human body. Although primarily intended for use in human joint replacement, the joints may also be designed for use in animals.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be better understood from the following detailed description of some preferred embodiments of the invention, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts, and in which:

Figure 1 is a perspective view of the two components of a preferred configuration of the joint, separated;

Figure 2 is an enlarged sectional view taken on line 2-2 of Figure 1, with the joint assembled;

Figure 3 illustrates diagrammatically one technique for physical vapor deposition of the surface coating on the joint;

Figure 4 illustrates the installation of the joint in a pelvis;

Figure 5 is a sectional view of a basic type of joint incorporating the coating;

Figure 6 is a perspective view of a metacarpophalangeal artificial joint according to another embodiment of the present invention;

Figure 6A is an exploded perspective view of the joint shown in Figure 6;

Figure 7 is a perspective view of an interphalangeal artificial joint according to another embodiment of the present invention;

Figure 7A is an exploded perspective view of the joint shown in Figure 7;

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Figure 8 is a perspective view of the skeletal structure of the fingers of a hand with implanted artificial joints of Figures 6 and 7;

5 Figure 9A is a cross-sectional view of the metacarpophalangeal artificial joint as seen along the line 9-9 in Figure 6, with the artificial joint in full extension;

Figure 9B is a view of the joint shown in Figure 9A with the joint in flexion;

10 Figure 10 is an exploded perspective view of the artificial joint of Figure 6 showing its modular construction;

15 Figures 11A and 11B are plan view of the base member of the metacarpophalangeal joint as seen along the line 11A-11A in Figure 6A;

Figure 11C is a plan view of the base member of the interphalangeal joint as seen along the line 11C-11C in Figure 7A; and

20 Figure 12 is an elevational plan view of a modified protraction member for the joint of Figure 6, with portions shown in phantom.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 Figures 1, 2 and 4 of the drawings illustrate a hip joint 200 according to a first embodiment of the present invention, while Figure 3 illustrates a coating method for forming a coating layer on the articulating surfaces, as will be described in more detail below. Although a hip
30 joint is illustrated in Figures 1, 2 and 4, it will be understood that this invention may also be applied to any other joint of the body, with suitable design of the articulating surfaces depending on the degrees of motion to be provided by the joint. Some joints, such as the hip
35 joint, are partially spherical ball and socket joints which allow for multi-directional or full, 190° articulation. Other joints, such as finger joints and knee joints,

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articulate in one or two directions, and prosthetic finger joints and knee joints must be designed to replicate the natural motion of such joints.

5 A natural hip joint comprises an acetabulum or acetabular cup in the lower region of the pelvis 210 into which the head or ball of the femur fits to form the articulating hip joint. The prosthetic hip joint 200 of Figures 1, 2 and 4 comprises a first, socket part or acetabular cup 212 for replacing the acetabulum and a
10 second, ball part 214 for articulating engagement in cup 212, for replacing the head of the femur.

The socket part 212 has a solid body with an outer, non-spherical or prolate ellipsoidal surface 216 having a major or central axis 218 and terminating in a transverse
15 end surface with a concave depression or seat 222. Seat 222 is part spherical and has a central axis 223 offset from the major axis 218, as best illustrated in Figure 2. The angle α between axis 218 and axis 223 is preferably of the order of 20° .

20 The ellipsoidal surface 216 is designed to fit closely into an ellipsoidal cavity which will be surgically machined into the pelvic bone, with the end surface and concave seat 222 exposed. The end surface comprises a flat annular rim 224 and an outwardly projecting, tapered rim
25 226 surrounding seat 222 for conformance with the surrounding pelvic structure. Tapered rim 226 is of varying thickness, with a maximum thickness forming a superior outer face 228 where the rim is at its widest and an inferior outer face 229 where the rim is recessed
30 inwardly. Face 228 preferably extends at an angle β of around 20° to a line perpendicular to rim 224, as illustrated in Figure 2. When the socket part is secured in the pelvic bone as illustrated in Figure 4, the superior outer face 228 will generally align with the ilium, and the
35 inferior outer face will generally align with the acetabular notch, while the socket or seat 222 faces

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generally downwardly in the appropriate orientation matching that of the natural acetabulum.

5 The ellipsoidal surface has a plurality of annular grooves 230, and has a relatively high surface roughness for better osseointegration with the surrounding bone. A rigid, elongate anchoring keel 232 extends from the ellipsoidal surface of the socket part 212. Keel 232 is channel-shaped, and has a flat base wall 234 and perpendicular side walls 235, 236. It is suitably secured
10 at one end to the ellipsoidal surface so that it extends at an angle γ to the major axis 218 of the ellipsoidal surface. Preferably, the angle γ is in the range of 42° to 45° . Keel 232 is aligned with the superior outer face 228 of the rim 226. A suitable stabilization channel (not
15 illustrated) will be machined to extend into the body of the ilium from the previously machined spherical cavity, at an appropriate angle and shape for receiving keel 232. Thus, the orientation of keel 232 selected will be dependent on the orientation of the iliac wing channel
20 relative to the socket machined in the pelvic bone. The socket part 212 is embedded in the machined socket with the keel 232 extending up into the channel, as illustrated in Figure 4. Since the load on the part 212 will be downwards, the keel will be locked firmly in the channel
25 and will lock the socket part in position. Keel is suitably welded to the ellipsoidal surface, by electron beam welding or the like.

The ball part 214 of the joint comprises a solid body having a convex or spherical surface 240 for articulating
30 engagement in socket or seat 222 and a flat end face 242 with a tapered bore 244 for receiving the tapered end portion 245 of a conventional stem 246 for embedding in a suitably machined bore in the patient's femur, as is conventional in the field of hip joint replacement. Stem
35 246 will be of the same material as ball part 214. Bore 244 has a so-called Morse taper matching the taper of end portion 245 so that the parts are locked together when the

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end portion 245 has been jammed or forced into bore or socket 244, as is known in the field.

5 The diameter of the concave or part spherical seat 222 is controlled to be slightly larger than the diameter of the convex surface 240 of the ball, preferably of the order of 0.003 inch larger than the ball diameter. Additionally, the convex surface 240 is machined to have a slightly different diameter in its lower half, adjacent the flat end face 242, than in the upper half above center line 248 as
10 viewed in Figure 2. Preferably, the diameter of convex surface 240 below center line 248 is around 0.001 inch less than the diameter of surface 240 above line 248. This arrangement will leave a small gap around the rim of the articulating surfaces to allow body fluid to enter and
15 lubricate the articulating surfaces, reducing wear.

The surgical procedure for implanting the cup or socket part 212 into the pelvis of a patient will be substantially as described in our co-pending application Serial No. 08/232,689 filed April 25, 1994, the contents of
20 which are incorporated herein by reference.

Preferably, both the socket part 212 and the ball part 214 are made of titanium alloy material, with a thin coating layer 250,252 of titanium nitride covering at least the concave seat 222 of socket part 212 and the convex
25 surface 240 of ball part 214, respectively. Although the entire outer surface of each joint part is covered with a thin coating layer, only the articulating surfaces 222 and 240 of the socket and ball parts may be covered with coating layers in an alternative embodiment, if desired.
30 As illustrated, each of the articulating surfaces is not a smooth or polished surface, but instead has a predetermined amount of surface roughness, allowing body fluid to flow between the opposing articulating surfaces.

Titanium alloy is a preferred material for making each
35 of the joint parts since it is strong, non-toxic, and resistant to deterioration. Additionally, it has a good affinity for bone, so that osseointegration occurs readily

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between the prosthetic joint part and the bone in which it is embedded. Preferably, the alloy is TiAl64 V, an alloy of titanium, aluminum and vanadium. Titanium nitride has been found to be the ideal material for the coating layer, since it is hard, biocompatible and extremely resistant to articulation on repeated articulation or sliding engagement between the surfaces over extended periods of time. The titanium nitride coating layer provides the necessary hardness to the articulating surfaces, and the opposing articulating surfaces will have the same hardness. Another advantage of using a titanium alloy substrate with a titanium nitride coating layer is that the titanium nitride material becomes completely integrated and locked into the titanium material of the substrate, further reducing the risk of chipping or flaking, which can otherwise be a problem with joints having a cover or coating layer over a metal substrate. The coating material may be TiN or TiNN (double nitride).

Another advantage of using identical materials for both the ball and socket part of the joint is that the lifetime of the joint will be extended over previous prosthetic joints where either the ball or the socket were of a softer, plastic material. Where the two articulating surfaces are of the same material having the same hardness, the risk of abrasion and articulation is reduced, and the lifetime of the joint will be increased. Thus, whereas the lifetime of a prosthetic joint in the past was only around five years, the joint of this invention is expected to last for the entire remaining lifetime of a patient, thus requiring only one surgery rather than several repeated surgeries.

The actual articulation or feel of the joint will also be improved and more natural than known joints having a ball and socket of different hardness. The articulating movement will be much smoother and less likely to jam or stick, and thus more comfortable for the patient.

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A preferred method of making the joint parts 212, 214 will now be described in more detail, with reference to Figure 3. The body of each joint part is first formed to the desired basic shape, either by machining from a billet of titanium alloy, or by casting or forging. The outer surface of the socket part is then bead-blasted to provide a very rough outer surface finish on the ellipsoidal surface 216, for better osseointegration or bone growth into the depressions on the roughened surface. The articulating concave and convex surfaces 222 and 240 are then diamond-lapped to form the precise spherical surface desired, and also to provide a predetermined surface roughness or finish. Preferably, each of the surfaces 222 and 240 has a #8 finish, and thus a small degree of surface roughness. In other words, neither of the surfaces 222 or 240 is a smooth polished surface.

At this point, the machined surfaces 222 and 240, at least, of each joint part are coated with a thin layer of titanium nitride. Alternatively, the entire outer surface of the respective joint parts may be coated with a thin layer of titanium nitride. Preferably, the coating layer is applied by a technique known as physical vapor deposition or PVD, as generally illustrated in Figure 3. In PVD, a substrate such as the ball part 214 of the joint is placed into a vacuum chamber 254. Vacuum chamber 254 is filled with a working gas, such as argon, to a pressure adequate to sustain a plasma discharge. A target 256 of the desired coating material, in this case titanium nitride, is also mounted in chamber 254 facing the substrate 214. A negative bias is applied to the target via power supply 258. The target 256 is thus bombarded with positive ions from the plasma, causing condensing of atoms of the coating material onto the substrate as indicated in Figure 3, forming the desired thin coating layer. The thickness of the coating layer is about 3 to 3.5 microns, so that it will adopt the same surface finish or roughness as the underlying surface of the substrate.

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The PVD technique for forming the coating layer has been found to provide a coating which is more firmly integrated with the underlying substrate and is less likely to particulate. Additionally, PVD will ensure that the coating layer conforms to the surface roughness of the underlying surface, and provides a precise and consistent coating layer over the entire articulating surface.

The same technique is used to coat at least the socket or concave surface 222 of socket part 212 with an equivalent thin layer 250 of titanium nitride. Alternatively, the entire outer surface of each part may be coated with a thin layer of titanium nitride for convenience and ease of manufacture.

Since the articulating surfaces have a small degree of surface roughness, pathways will be provided for body fluids to flow between the articulating surfaces, thus lubricating the surfaces continuously and resisting wear and sticking of the joint. This provides for a better and smoother articulation of the joint, as well as reduced wear and thus a longer lifetime for the joint. It also reduces the risk of particulation or flaking of either surface.

The material and surface finish of the two joint parts as illustrated in Figures 1, 2 and 4 may also be used advantageously on any other joint for replacing any joint in the body. Figure 5 illustrates a different prosthetic hip joint 260 which may be used in place of joint 200 and which is made of the same materials and with the same surface finish as joint 200. Joint 260 also comprises a socket part 262 and a ball part 264 each made of titanium alloy, preferably TiAl64V. The socket part 262 may be shaped for fitting into a suitably machined cavity in the pelvis, and may be secured in the cavity in any suitable manner, either with or without an anchoring keel as in the previous embodiment. The part 262 has an outer end face 265 with a part spherical socket or seat 266 for replacing the natural acetabular cup. The entire outer surface of part 262 is sputter coated with a thin layer 268 of

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titanium nitride or double nitride, and has a #8 finish or equivalent surface roughness. The ball part 264 is also made of the same titanium alloy as socket part 262 and has a ball head 270 for articulating engagement in socket 266, and a stem 272 for securing to the femur. At least the head 270 is coated with a thin layer 274 of titanium nitride or double nitride by PVD, and has a surface roughness identical to that of seat 266.

By making both the ball and socket of a prosthetic joint of the same titanium alloy with the same titanium nitride coating layer, and also providing a predetermined, non-smooth surface finish on each of the articulating surfaces, a prosthetic joint of improved operation and significantly increased lifetime is provided. The surface roughness ensures adequate lubrication of the joint at all times, reducing the risk of abrasion or particulation. These substrate and coating materials may be used in making a prosthetic joint for use elsewhere in the body, such as a knee joint as described in our U.S. Patent No. 5,370,700, a finger joint, ankle joint, shoulder joint, jaw joint, wrist joint, toe joint, and so on, using the same manufacturing process as described above in connection with Figure 3, but with the appropriate shapes of the articulating surfaces matching the shape of the particular joint to be replaced, or duplicating the articulating motion of the natural joint.

Figures 6-12 illustrate finger joints according to another embodiment of the invention which are made of the same materials as the hip joints of Figures 1-5. The skeletal structure 62 of the hand is illustrated in Figure 8. Each finger includes a number of bones connected together by joints. A metacarpophalangeal (MCP) joint 67 is provided between metacarpal bone 66 and the proximal or first phalanx 68. An interphalangeal (IP) joint 69 is provided between the proximal phalanx and middle or second phalanx 70, and between the second and third phalanges 70 and 71 on each finger. Each MCP joint must allow for

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various types of articulation. First, it must allow articulation in the plane of the finger, or extension and flexion movement of the finger in the direction of arrows 30 and 32 in Figure 6. Secondly, it must allow the finger to move from side to side through a certain angle, as indicated by the arrows 32 and 34. Thirdly, some degree of axial rotation of the finger about joint 67 is permitted, in the direction of arrow 38. Each IP joint is only required to articulate in one direction, co-planar with the axis of the finger in the direction of arrows 58 and 60 in Figure 7. Thus, two types of prosthetic finger joint are provided. Figures 6, 6A, 9A and 9B illustrate a prosthetic MCP joint 10 for replacing a natural MCP joint 67, while Figures 7, 7A and 11C illustrate a prosthetic IP joint 40 for replacing any of the natural IP joints 67 of a finger or thumb.

As shown, the MCP joint 10 includes a protraction member 12 which abuts and is slidably engaged with a base member 14. Importantly, the surfaces of protraction member 12 and base member 14 are appropriately dimensioned to establish a separation of approximately fifteen ten thousandths of an inch (0.0015 inch) therebetween. This is done in order to allow synovial fluid to flow between the members 12,14 to provide lubrication in the joint 10.

As perhaps best seen in Figure 6A, a pair of substantially parallel arms 16a and 16b, extend from protraction member 12. The arms 16a,b are formed with barbs 18 which assist in the fixation of protraction member 12 to the skeletal structure of the person receiving the implant of artificial MCP joint 10. Figure 6A also shows that protraction member 12 is formed with a rounded, substantially hemispherical, convex articular engaging surface 20, and that the articular surface 20 is formed with a circumferential groove 22. To be engageable with protraction member 12, the base member 14 of MCP joint 10 is formed with a recessed, substantially hemispherical, concave articular receiving surface 26 which is dimensioned

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to slidably receive the engaging surface 20 of protraction member 12. Additionally, a mounded protrusion 28 extends outwardly from the recessed articular receiving surface 26 of base member 20 for insertion into the groove 22 when
5 base member 14 is engaged with protraction member 12.

Returning to Figure 6, it is to be appreciated that MCP joint 10 for the present invention is intended to allow movement of the finger distally from joint 10 in extension-flexion as indicated by the arrows 30/32. Specifically,
10 extension of the finger is accomplished by movement in the direction of arrow 30, while flexion is accomplished by movement in the direction of arrow 32. Simultaneously, MCP joint 10 is intended to allow lateral rotation at the joint 10 in the directions indicated by the arrow 34/36. Also,
15 and again simultaneously with the other possible movements, MCP joint 10 is intended to allow axial rotation of the finger distal to joint 10 in the directions indicated by the arrow 38. All of the above-described movements result from the interaction between the protrusion 28 of base
20 member 14 and the groove 22 of protraction member 12 as the members 12 and 14 slidably abut each other. The exact manner for this interaction is to be subsequently discussed.

Figure 7 shows an artificial interphalangeal (IP) joint in accordance with the present invention which is
25 generally designated 40. IP joint 40 is shown to include a base member 42 and a protraction member 44. With a structure similar to that previously disclosed for MCP joint 10, IP joint 40 also has barbed arms 46a,b and barbed
30 arms 48a,b which extend respectively from protraction member 44 and from base member 42. Also, similar to the protraction member 12 of MCP joint 10, protraction member 44 of IP joint 40 is formed with a rounded, substantially hemispherical, convex articular engaging surface 50 having
35 a circumferential groove 52. Base member 42 of IP joint 40, however, differs somewhat from base member 14 of MCP joint 10. Although base member 42, like base member 14, is

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formed with a recessed, substantially hemispherical, concave articular receiving surface 54, unlike base member 14, the base member 42 of IP joint 40 has a ridge-like protrusion 56 which extends from its articular receiving surface 54 for insertion into groove 52 of protraction member 44. More specifically, the protrusion 56 is dimensioned for a snug fit into the groove 52 so that protrusion 56 is confined to only linear movement along the groove 52. The consequences of this structural interaction is best shown in Figure 7.

From Figure 7 it is to be appreciated that the relative movement between base member 42 and protraction member 44 is, as indicated by the arrows 58/60, is limited to only in flexion-extension. This is so because of the confined movement of protrusion 56 along the length of groove 52. More specifically, due to the snug fit between protrusion 56 and groove 52, protrusion 56 is unable to rotate within the groove 52.

In Figure 8 the skeletal structure for part of a patient's hand is shown and generally designated 62. There it will be seen that an MCP joint 10 is inserted into a finger 64 between the metacarpal bone 66 and the proximal phalanx 68. Also, it will be seen that an IP joint 40 is inserted into another finger in the skeletal structure 62 between the proximal and middle phalanges 70/72. In each instance the joint 10 or 40 is enclosed in the skeletal structure 62 by inserting their respective barbed arms into the adjoining bone structure. The particular procedure for accomplishing this operation is left to the discretion of the surgeon and is not necessary for an understanding of the present invention.

Each of the artificial finger joints 10 and 40 is preferably made of the same materials as the hip joint 200 of the previous embodiment, as best illustrated in Figures 9A and 9B. The MCP joint 10 is illustrated in Figures 9A and 9B, but it will be understood that the IP joint will be made of the same material. As in the previous embodiment,

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each of the two joint halves or parts 12 and 14 is made of titanium alloy material, preferably TiAl64V. The barbed arms 16a,16b,24a and 24b are preferably made of the same titanium alloy. The joint parts 12 and 14 are coated with
5 a thin layer 74 of titanium nitride or double nitride, preferably using a physical vapor deposition technique as described above in connection with Figure 3. Preferably, at least the articulating surfaces 20,22,26,28 of the joint parts have a non-smooth finish, preferably a #8 finish, and
10 the slight degree of surface roughness between the articulating surfaces will help to ensure that the surfaces are adequately lubricated. The thickness of the coating layer is preferably around 3 to 3.5 microns, as in the previous embodiments. The IP joint 40 will also be of the
15 same titanium alloy and will have a coating layer of the same material on at least its articulating surfaces, as well as the same surface roughness on the articulating surfaces as in joint 10.

Figure 10 shows the modular feature of the present invention as incorporated into the MCP joint 10. Though
20 MCP joint 10 is specifically considered here, it is to be understood that this modular feature also applies equally to the IP joint 40. As shown in Figure 5, base member 14 is interlockingly engageable with an attachment 76. More
25 specifically, arms 24a,b extend from the attachment 76 and the attachment 76 is formed with an angled slot 78 which is dimensioned to receive the angled projection 80 that is formed as part of base member 14. Similarly, protraction member 12 is interlockingly engageable with an attachment
30 82. Also similarly, arms 16a,b extend from the attachment 82 and the attachment 82 is formed with an angled slot 84 which is dimensioned to receive the angled projection 86 that is formed as part of the protraction member 12.

For the preferred embodiment of the present invention,
35 the interlockability of base member 14 with attachment 76, and the interlockability of protraction member 12 with attachment 82, is best seen in Figure 10. There it is

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shown that the angled slot 78 of attachment 76 is actually tapered so that the width of the angled slot 78 is less or narrower at its end 92 than at its end 94. The angled projection 80 of base member 14 is compatibly dimensioned to receive the angled slot 78 of attachment 76. Accordingly, the end 96 of angled projection 80 is substantially the same size as the end 92 of angled slot 78. In a similar manner the angled projection 86 is tapered and compatibly dimensioned to be received into the angled slot 84 of attachment 82. Specifically, end 98 of angled projection 86 is wider than the end 100 of the projection 86, and the end 100 is substantially the same size as the width of angled slot 84 at its end 102. It will be appreciated by the skilled artisan that with the tapers oriented as shown, the protraction member 12 and base member 14 will resist each other whenever there is relative lateral motion between them. With this modularity, the articular surfaces of both base members 14,42 and protraction members 12,44, as well as the members themselves, can be sized and dimensioned as desired to account for bone resection and ligament balancing.

Turning for the moment to Figure 12, some of the more subtle structural characteristics of the present invention will be appreciated. Although protraction member 12 of the MCP joint is shown, it is only exemplary and these subtleties apply equally to the base member 14 of the MCP joint, as well as to the IP joint and to the modular embodiments of the present invention. First, it will be seen that the base member 12 is formed with holes 104 and 106, and that these holes lead into channels 108 and 112 (shown in phantom) which exit from the base member 12 at other holes (not shown). Frequently, as is well known in the pertinent art, an artificial joint 10,40 requires ligament attachment. Accordingly, the purpose of the holes 104,106 and their channels 108,112 is to allow for the replacement of diseased or deficient ligaments with suitable sutures.

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Figure 7 also shows that the barbs 18 on arms 16a,b are outwardly angled, and away from the opposing arm 16, through an angle 114. For purposes of the present invention the angle 114 may be in the range of from 15° to 50°. Further, Figure 7 shows that the arms 16a,b are towed-in relative to each other. More specifically, the distance 116 between the exposed ends of the arms 16a,b is less than the distance 118 between the ends of the arms 16a,b which are attached to the protraction member 12. The outwardly angled barbs 18 provide additionally anchorage for the members by helping to prevent the thin edge of arms 16 from cutting into the bone. Together, the outwardly angled barbs 18 and the tow-in feature of the arms 16a,b help inhibit an abnormal erosion of the bony canal into which the arms 16 of the joint 10,40 anchored. This improves both the anchorage of the join 10,40 and its longevity.

As stated above, articulation of MCP joint 10 involves flexion-extension, lateral rotation, and axial rotation. These various movements are best appreciated by cross-referencing between several figures. To begin, consider the flexion-extension motion of MCP joint 10 and refer to Figures 6, 9A and 9B. As indicated above, and shown in Figure 6, extension is accomplished by movement in the direction of arrow 30 and flexion is accomplished by movement in the direction of arrow 32. Figures 9A and 9B show that during a flexion-extension movement of joint 10, the mounded protrusion 28 of base member 14 moves linearly along the groove 22 of protraction member 12. Also, as with all operational functions of the joint 10, base member 14 is juxtaposed and slidably engaged with protraction member 12. For purposes of the present invention, groove 22 should be of sufficient length to allow for flexion-extension movement in the directions of arrows 30/32 through a range of approximately 150°.

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Lateral rotation of MCP joint 10 is best appreciated by cross-referencing Figure 6A and Figure 11A. In Figure 6A the opposing edges of groove 22 are numerically identified as 88a and 88b. In Figure 11A, the edges 88a and 88b are shown in phantom as they would be located on the recessed articular receiving surface 26 of base member 14. As shown in Figure 11A, the edges 88a and 88b are distanced from each other by a spacing 90. Further, for MCP joint 10, spacing 90 is sufficiently larger than the dimensions of protrusion 28 to permit a selective movement of protraction member 12 between spacing 90' and spacing 90". This results in a lateral rotation of protraction member 12 relative to base member 14 in the directions of arrows 34/36 through a range of approximately 50°.

Axial rotation of MCP joint 10 is best appreciated by cross-referencing Figure 6A with Figure 11B. In this case, the size of protrusion 28 is seen to be such that protraction member 12 is able to axially rotate relative to base member 14 in the direction of arrow 38. Specifically, as seen in Figure 11B, spacing 90 between the edges 88a,b is sufficiently larger than the dimensions of protrusion 28 to permit a selective movement of protraction member 12 between spacing 90" and 90"". This results in an axial rotation of protraction member 12 relative to base member 14 in the direction of arrow 38. For purposes of the present invention, axial rotation of the protraction member 12 is preferably in the range of approximately 50°.

It is to be appreciated that flexion-extension, lateral rotation, and axial rotation of protraction member 12 relative to base member 14 can be accomplished either independently or simultaneously in concert with any of the other movements. IP joint 40, on the other hand, is more constrained.

Cross-referencing Figure 7A with Figure 11C shows that for IP joint 40, the ridge-like protrusion 56 on base member 42 fits snugly within the groove 52 of protraction member 44. The result is that there can be no lateral

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rotation or axial rotation of protraction member 44 relative to base member 42. Instead, only flexion-extension movement is possible. In all other respects, to include incorporation of a protective coating 74 and the modularity feature disclosed above, IP joint 40 is substantially similar to MCP joint 40.

Although the invention has been described above as applied to a hip joint and two different types of finger joint, it will be understood that the same materials may be advantageously used for an implantable joint to replace any damaged articulating joint in the body. In each case, use of a substrate of titanium alloy for each part of the joint, with a coating of titanium nitride covering at least the articulating surface of each opposing joint part, has been found to produce a joint which has a much longer effective lifetime, is more biocompatible, and is less likely to particulate than previous prosthetic joints. The combination of titanium alloy substrate which has a predetermined surface roughness, with a thin layer of titanium nitride applied over the roughened surface so that it adopts the contour of the underlying surface, has been found to promote full integration and anchoring of the coating layer onto the underlying substrate, so that the risk of particulation or flaking is substantially reduced.

Although some preferred embodiments of the present invention have been described above by way of example only, it will be understood by those skilled in the field that modifications may be made to the disclosed embodiments without departing from the scope of the invention, which is defined by the appended claims.

WE CLAIM:

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CLAIMS

1. A prosthetic joint, comprising:
 - 5 a first, socket part having an at least partially concave articulating surface;
 - a second part having an at least partially convex articulating surface for rotatable seating engagement in said concave articulating surface;
 - 10 both parts of the joint being of titanium alloy having the same hardness; and
 - a coating layer of titanium nitride covering at least the articulating surface of each joint part.
- 15 2. The joint as claimed in claim 1, wherein the titanium alloy is an alloy of titanium, aluminum and vanadium.
3. The joint as claimed in claim 2, wherein the alloy is TiAl64V.
- 20 4. The joint as claimed in claim 1, wherein the titanium nitride is TiN.
5. The joint as claimed in claim 1, wherein the titanium nitride is TiNN.
- 25 6. The joint as claimed in claim 1, wherein said coating layer covers the entire outer surface of each joint part.
7. The joint as claimed in claim 1, wherein each articulating surface is a non-smooth surface having a predetermined roughness.
- 30 8. The joint as claimed in claim 7, wherein the articulating surfaces each have a #8 finish.

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9. The joint as claimed in claim 7, wherein each joint part has an outer surface for embedding in a patient's bone at a joint site, the outer surface having a rough surface which is rougher than said articulating surface.

5

10. The joint as claimed in claim 1, wherein the thickness of the coating layer is in the range from 3 to 3.5 microns.

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11. The joint as claimed in claim 1, wherein said concave surface comprises part of a spherical surface having a first diameter and said convex surface comprises at least part of a spherical surface for articulating engagement in said concave surface, the diameter of said convex surface being slightly less than said first diameter.

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12. The joint as claimed in claim 11, wherein said second part has a first end for engagement in said concave surface and a second end for attachment to an adjacent bone structure, a first portion of said convex surface adjacent said first end having a second diameter less than said first diameter and a second portion of said convex surface adjacent said second end having a third diameter less than said second diameter.

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13. The joint as claimed in claim 12, wherein said second diameter is 0.003 inch less than said first diameter and said third diameter is 0.001 inch less than said second diameter.

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14. The joint as claimed in claim 1, wherein said first, socket part comprises an artificial acetabular cup attachable to a pelvic bone and the second part comprises an artificial femur head attachable to a femur to form an artificial articulating hip joint.

15. The joint as claimed in claim 1, wherein the first, socket part comprises a first half of an artificial finger joint for attachment to a first finger bone and the second part comprises a second, mating half of an artificial finger joint for attachment to a second, adjacent finger bone for providing finger joint articulation with said first half.

16. A method of making a prosthetic joint for replacing an existing joint in the body, comprising the steps of:

forming two mating parts of a prosthetic joint from titanium alloy material, one part of the joint having an at least partially concave, articulating seating surface corresponding to the joint seating surface of a joint to be replaced and the other part of the joint having an at least partially convex articulating surface for articulating engagement in said seating surface and corresponding to the ball surface of a joint to be replaced;

machining the articulating surface of each joint part to a predetermined surface roughness, whereby the articulating surfaces are not completely smooth; and

coating at least the articulating surface of each joint part with a thin layer of titanium nitride which follows the underlying surface contour to provide a coating layer of the same roughness as the underlying titanium alloy surface, whereby the coating layer is integrated with the underlying surface.

17. The method as claimed in claim 16, wherein the convex articulating surface is machined to have two different diameters, the articulating surface having a first end for engaging in the seating surface and a second end for attaching to an adjacent bone structure, a first portion of the articulating surface adjacent said first end being machined to a first diameter slightly less than the diameter of the seating surface and a second portion of the articulating surface adjacent said second end being

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machined to a second diameter slightly less than the first diameter.

18. The method as claimed in claim 16, wherein the
5 articulating surface is machined to a #8 finish.

19. The method as claimed in claim 16, wherein the coating layer is applied by physical vapor deposition.

10 20. A prosthetic hip joint, comprising:

a first, socket part having a first portion for attachment in a machined cavity in a pelvic bone and a second, outer end portion having a concave recess forming an articulating seating surface;

15 a second, ball part having a convex, articulating surface for rotatable seating engagement in said articulating seating surface and an outer end for attachment to a femur to replace the head of the femur;

20 said ball part and socket part being of the same material and said articulating surfaces having the same hardness; and

25 each of said articulating surfaces being non-smooth and being machined to a predetermined roughness, whereby openings are provided between the articulating surfaces for allowing body fluids to lubricate the joint.

21. The joint as claimed in claim 20, wherein each articulating surface has a #8 finish.

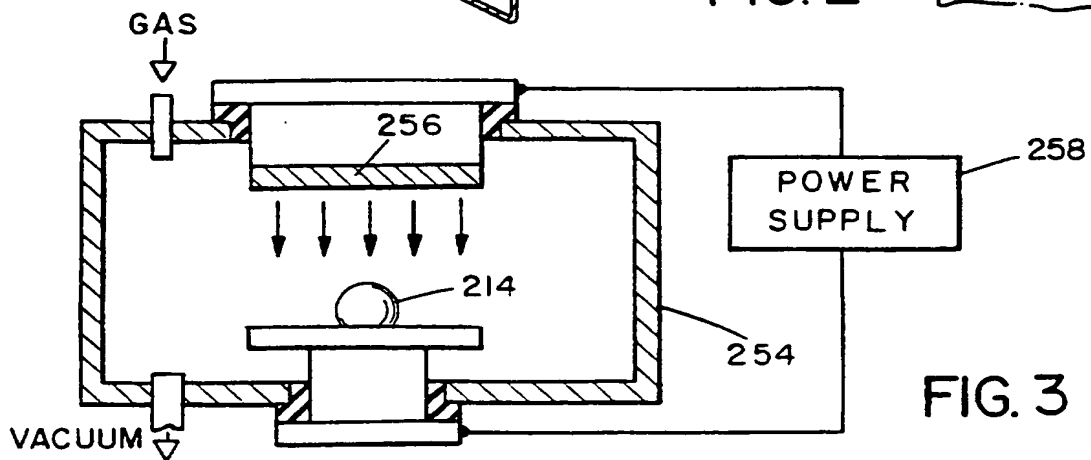
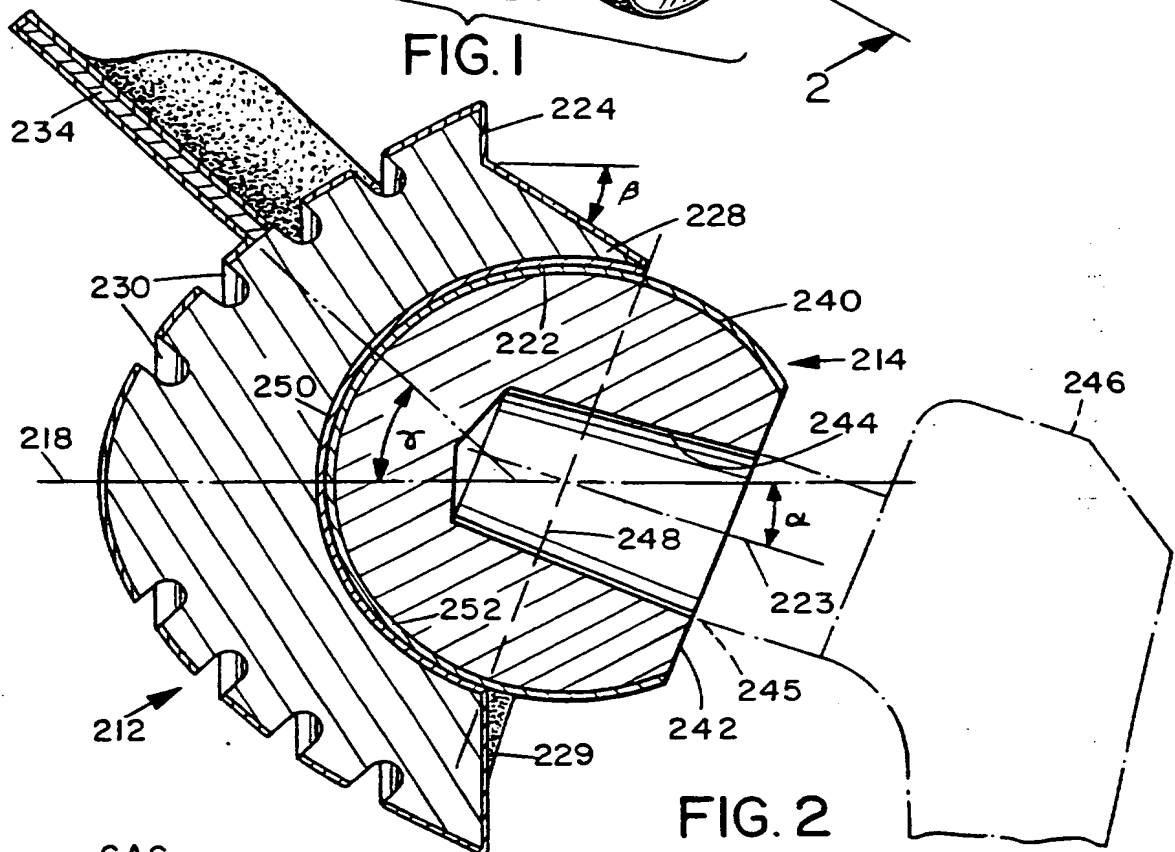
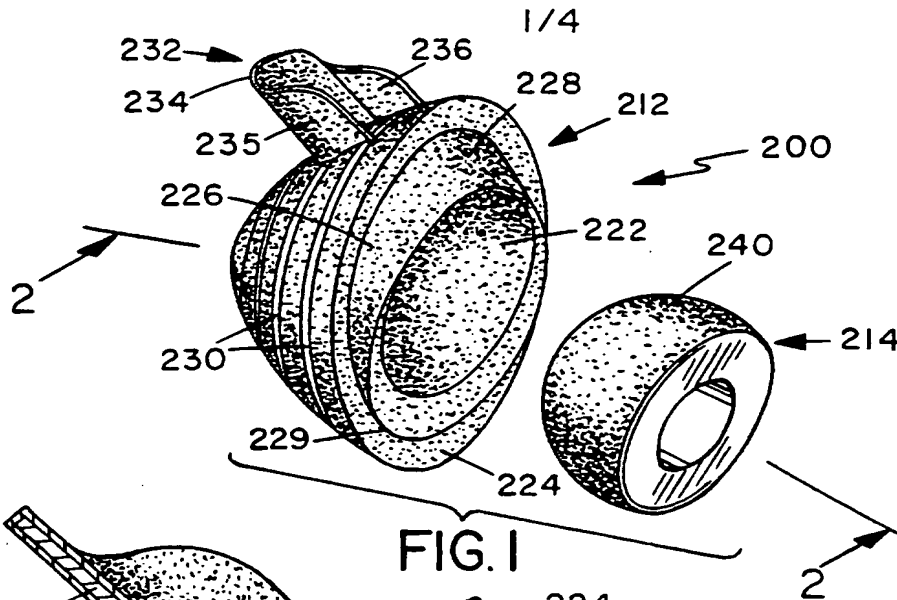
30 22. The joint as claimed in claim 20, wherein the first portion of the socket part has a non-spherical, ellipsoidal outer surface having a major axis, and the concave recess has a central axis at an angle to said major axis.

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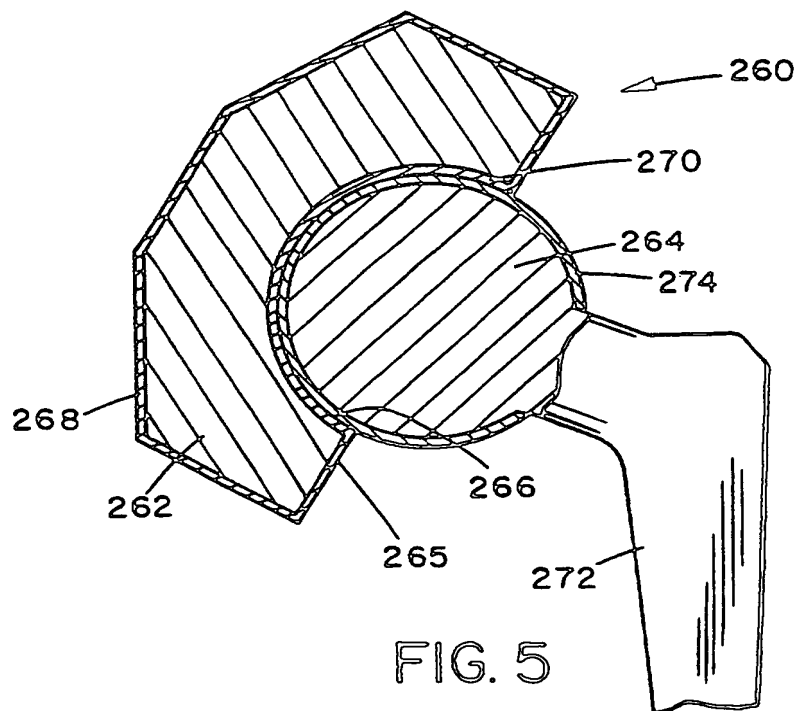
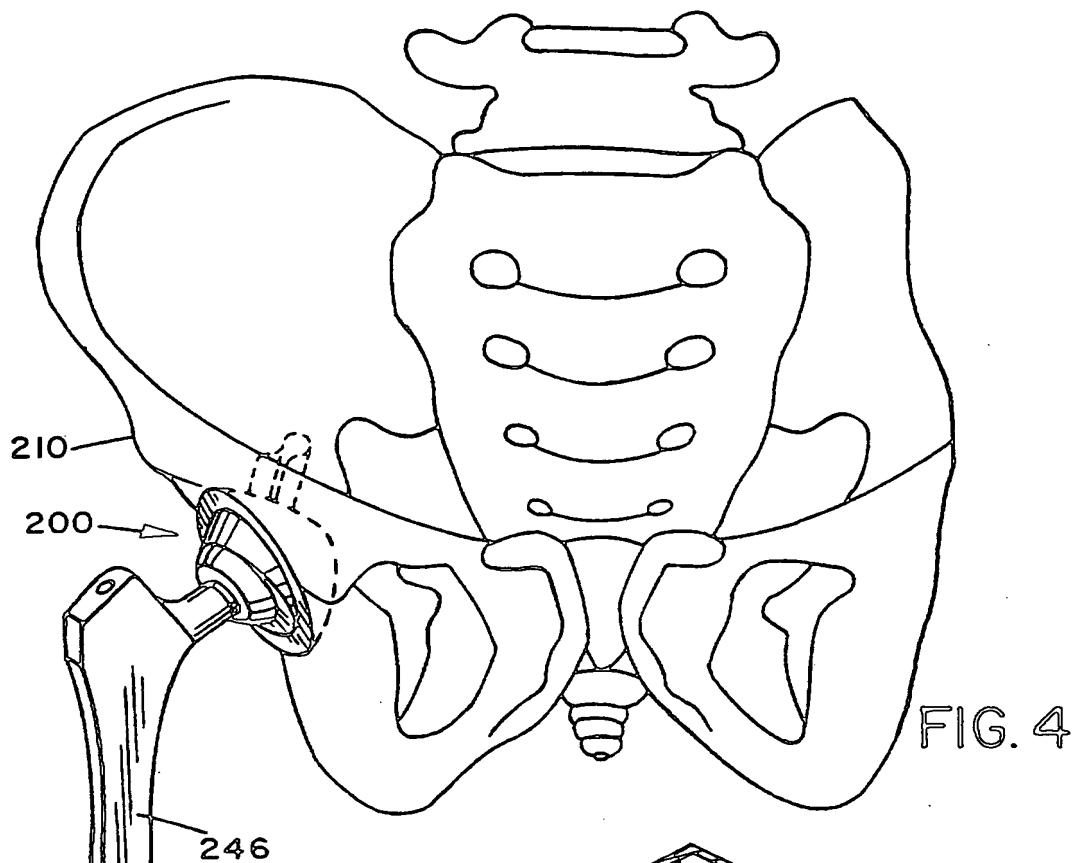
23. The joint as claimed in claim 20, wherein the first portion of the socket part has a non-spherical, ellipsoidal outer surface which is roughened to a predetermined surface roughness greater than the roughness of said articulating surfaces.

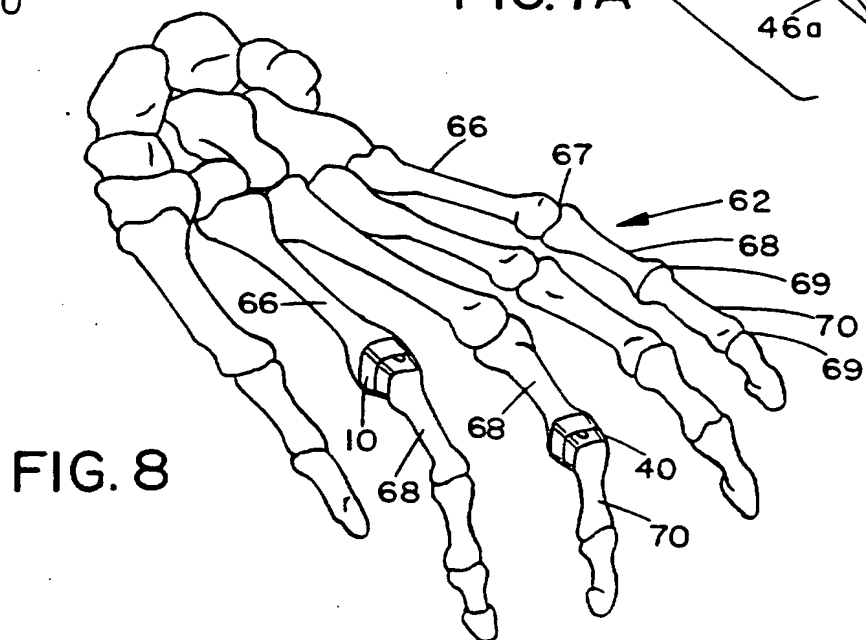
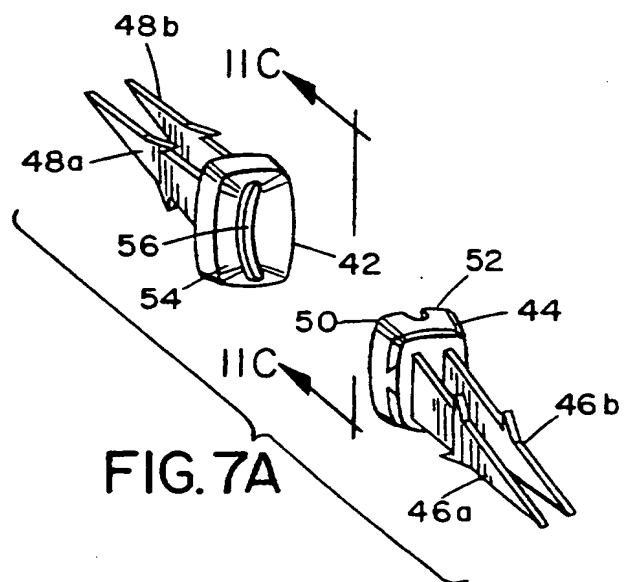
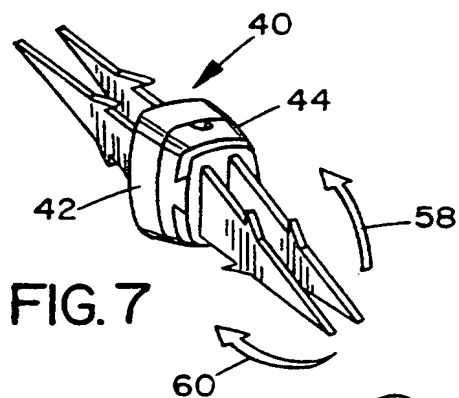
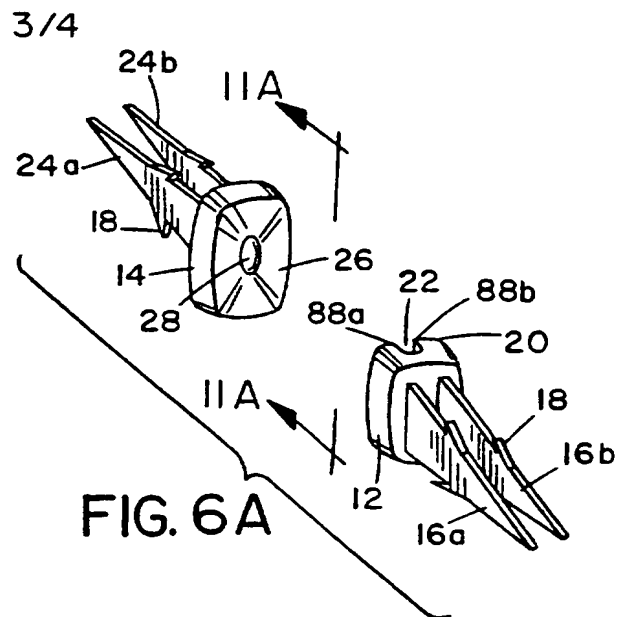
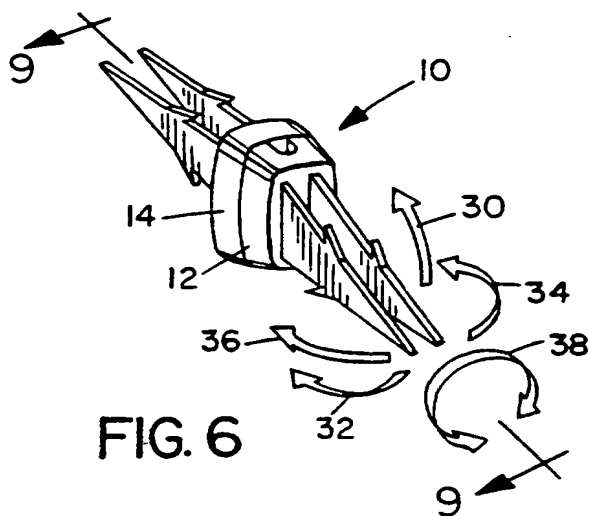
24. The joint as claimed in claim 20, wherein said concave seating surface comprises a spherical surface of constant diameter, and said convex articulating surface comprises a spherical surface having a first spherical portion of a first diameter for engaging in said recess and a second portion of a second diameter smaller than said first diameter adjacent said outer end, said second portion comprising means for forming a gap between said second portion and opposing portions of said seating surface for allowing body fluids to enter the joint and lubricate the articulating surfaces.

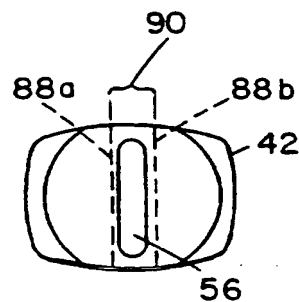
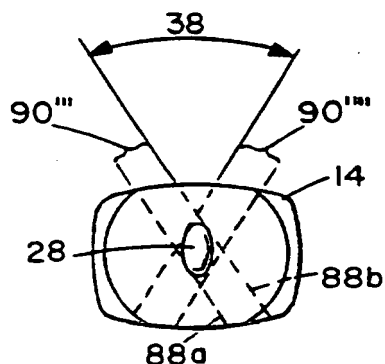
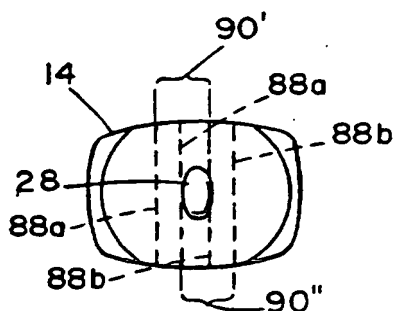
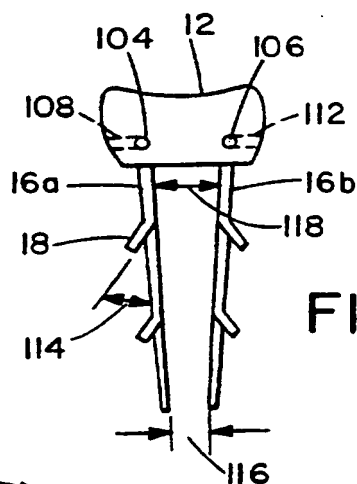
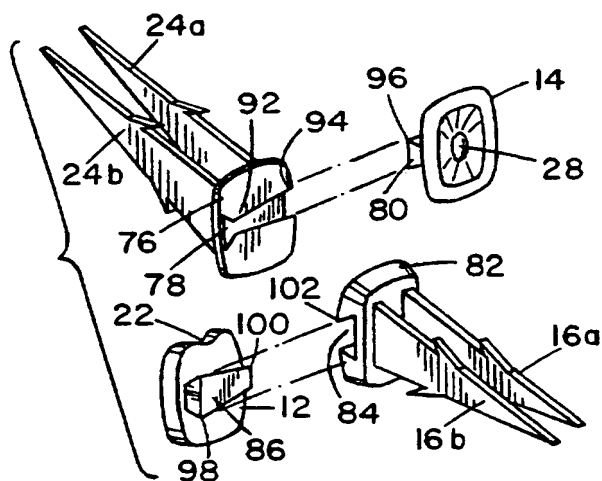
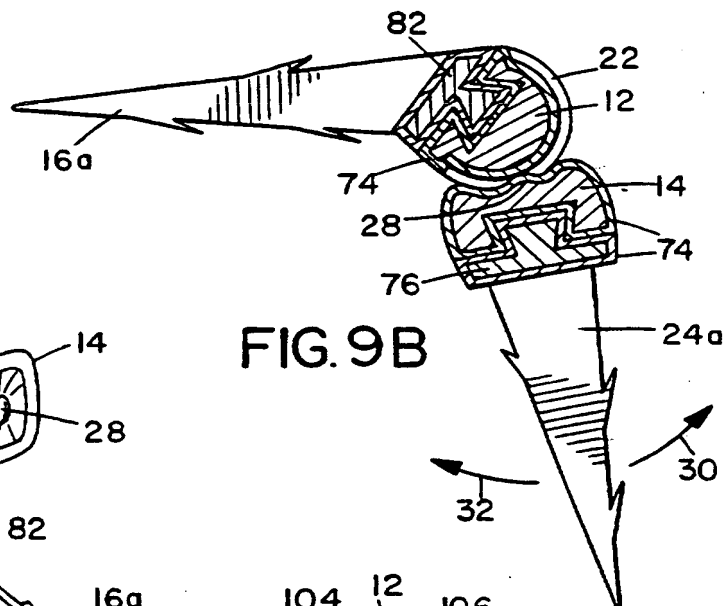
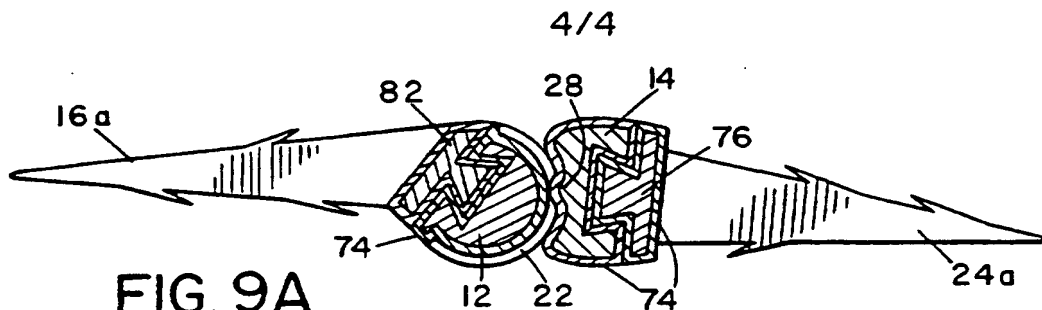
25. The joint as claimed in claim 20, wherein each of said parts is of titanium alloy and has a coating layer of titanium nitride covering at least said articulating surface.



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/16751

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/30 A61L27/00 A61F2/32 A61F2/42 C23C14/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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A	see column 7, line 14 - column 8, line 12; claims 1-4,10; figures 1,2	5,10,16
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

6 March 1997

Date of mailing of the international search report

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